

NOV 17 2003

510(k) Notification  
Unotech Diagnostics Inc.  
AccuTest™ hCG-Combo  
AccuStrip™hCG-Combo  
September 22, 2003

K032987

**510(k) Summary of Safety and Effectiveness  
Substantial Equivalence Discussion**

Trade or Proprietary Name: AccuTest™ hCG-Combo  
AccuStrip™ hCG-Combo

Common or Usual Name: Human Chorionic Gonadotropin Test System

Product Classification No.: 21 CFR §862.1155, Class II

Manufacturer: Unotech Diagnostics Inc.  
2235 Polvorosa Avenue, Suite 220  
San Leandro, CA 94577

Contact Person: Ken Wu, Ph.D.  
President  
Phone: (510) 352-3070

We conducted a comparison study with Unotech's AccuTest™ hCG-Combo, AccuStrip™ hCG-Combo and Quidel's QuickVue hCG Combo Test. A total of 181 specimens (94 urine specimens and 87 serum specimens) from patients seeking confirmation of pregnancy were tested simultaneously with AccuTest™ hCG-Combo, AccuStrip™ hCG-Combo and QuickVue hCG Combo tests. Test results show that both Unotech's AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo have 100% agreement with the Quidel QuickVue hCG Combo Test. Table 1A shows the test results of comparison study with urine specimens. Table 1B shows the test results of comparison study with serum specimens.

Table 1A: Comparison of AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo with the Quidel QuickVue hCG Combo Test Using Urine Specimens

	Unotech AccuTest™ hCG-Combo	Unotech AccuStrip™ hCG-Combo	Quidel QuickVue hCG Combo
Positive	48	48	48
Negative	46	46	46

Table 1B: Comparison of AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo with the Quidel QuickVue hCG Combo Test Using Serum Specimens

	Unotech AccuTest™ hCG-Combo	Unotech AccuStrip™ hCG-Combo	Quidel QuickVue hCG Combo
Positive	42	42	42
Negative	45	45	45

The following experiments were carried out to evaluate the sensitivity of AccuTest™ hCG-Combo, and AccuStrip™ hCG-Combo at low end and high end levels of hCG. Pooled negative urine and serum specimens were spiked with hCG to the concentrations of 0, 25, 50,  $10^4$ ,  $5 \times 10^5$  and  $10^6$  mIU/mL and tested with AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo. A total of 60 urine samples and 60 serum samples were blind labeled and tested with the AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo. Test results obtained from these experiments are the same using AccuTest™ hCG-Combo or AccuStrip™ hCG-Combo Tests with serum or urine specimens. The results are presented in Table 2.

Table 2: Sensitivity Test Results

hCG (mIU/mL)	0	25	50	$10^4$	$5 \times 10^5$	$10^6$
# of samples	10	10	10	10	10	10
Positive	0	10	10	10	10	10
Negative	10	0	0	0	0	0

The results demonstrate that the Unotech AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo can detect hCG in urine or serum at levels as low as 25 mIU/mL and as high as 1,000,000 mIU/mL.

These results establish that the Unotech AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo are substantially equivalent to the Quidel QuickVue hCG Combo Test.

The intended use of the Unotech AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo is for the early detection of pregnancy by the qualitative determination of human chorionic gonadotropin (hCG) in human urine or serum. Our intent is to market these products to clinical laboratories in the U.S.A. as well as in the foreign countries.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

NOV 17 2003

Ken Wu, Ph.D.  
President  
Unotech Diagnostics Inc.  
2235 Polvorosa Avenue – Suite 220  
San Leandro, CA 94577

Re: k032987  
Trade/Device Name: Unotech Accutest™ hCG-Combo and Accustrip™ hCG-Combo  
Regulation Number: 21 CFR 862.1155  
Regulation Name: Human chorionic gonadotropin (hCG) test system  
Regulatory Class: Class II  
Product Code: JHI  
Dated: September 22, 2003  
Received: September 26, 2003

Dear Dr. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

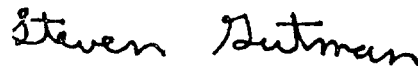
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

Page 1 of 2

510(k) Number (if know): N/A

Device Name: Accutest hCG-Combo

Indications For Use:

The intended use of the Unotech Accutest hCG-Combo is for the qualitative determination of human chorionic gonadotropin (hCG) in human urine or serum for the early detection of pregnancy.

Carol Benson for Jean Cooper, DVM  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K032987

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGES  
IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

510(k) Number (if know): N/A

Device Name: Accustrip hCG-Combo

Indications For Use:

The intended use of the Unotech Accustrip hCG-Combo is for the qualitative determination of human chorionic gonadotropin (hCG) in human urine or serum for the early detection of pregnancy.

Carol C. Benson / Jean Cooper, OVM  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K032987

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGES  
IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)